PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference E0006UP04W	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/JP2005/005217	International filing date *(day/month/year)* 23 March 2005 (23.03.2005)	Priority date *(day/month/year)* 26 March 2004 (26.03.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant Eisai R&D Management Co., Ltd.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 19 October 2006 (19.10.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Yoshiko Kuwahara e-mail: pt07@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)*
Applicant's or agent's file reference **E0006UP04W**	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2005/005217	**23.03.2005**	**26.03.2004**

International Patent Classification (IPC) or both national classification and IPC

Applicant
EISAI CO., LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☒ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP	Authorized officer
Facsimile No.	Telephone No.

WRITTEN OPINION OF THE
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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
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Box No. V **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	2-4, 6, 11, 15-19. 21-24, 26-28	YES
	Claims	1, 5, 7-10, 12-14, 20, 25, 29-30	NO
Inventive step (IS)	Claims		YES
	Claims	1-30	NO
Industrial applicability (IA)	Claims	1-30	YES
	Claims		NO

2. Citations and explanations:

Document 1: JP 8-506802 A (Andrx Pharmaceuticals, Inc.) 23 July 1996
Document 2: WO 03/43661 A1 (Eisai Co., Ltd.) 30 May 2003
Document 3: JP 2001-55322 A (Tanabe Seiyaku Co., Ltd.) 27 February 2001
Document 4: JP 2000-128779 A (Mitsui Chemicals, Inc.) 9 May 2000

(i) Based on the description in document 1 cited in the international search report, the inventions of claims 1, 5, 7-10, 12-14, 20, 25, 29 and 30 lack novelty and an inventive step.

Document 1 describes a pharmaceutical preparation providing a core comprising a drug and a swelling agent and the like, and a coating comprising a water-insoluble, ethacrylic acid copolymer that dissolves gradually in intestinal fluids, and magnesium stearate that coats the aforementioned core (example 1).

In addition, because the description of this application defines "disintegrant" as "a substance having the property of absorbing water and expanding in volume," this authority finds that the "swelling agent" of the invention described in document 1 is equivalent to the "disintegrant" of the inventions of this application.

(ii) Based on the descriptions in documents 2-4 cited in the international search report, the inventions of claims 1-30 lack an inventive step.

Document 2 describes a pharmaceutical composition comprising a core containing an acid-unstable physiologically active compound such as lansoprazole and the like and crospovidone, and a film containing a mixture of a water-insoluble polymer with an enteric polymer that coats the aforementioned core (claims 1 and 10). In addition, document 2 stated that a plasticizer can also be contained in the film (claims 3 and 7), that an alkaline substance can also be contained in the film (claims 4 and 8), and that ethyl cellulose and the like can be used as the water-insoluble polymer, and that Eudragit L100 and the like can be used as the enteric polymer (example 1; claims 5 and 6). Document 3 describes a pulse-release type preparation wherein a core substance containing a drug and a water-swelling substance is coated with a film containing an enteric polymer and a water-insoluble polymer (claim 1). In addition, document 3 states that the water-swelling substance is a disintegrant (claims 7-9), and that ethyl cellulose and the like can be used as the water-insoluble polymer and Eudragit L100 and the like can be used as the enteric polymer example 1, claims 11-13).

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Box No. VIII **Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 30 contains the statement "method for controlling leaching," but because this statement can be interpreted as a method for producing a controlled-leaching preparation and also as a method for controlling leaching of a physiologically active substance in the human body, which includes the step of administering a pharmaceutical preparation to the human body, this authority finds that the description of this claim is vague.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V.

Document 4 describes a tablet preparation wherein a core tablet comprising a drug and a water-swelling substance is coated with a film for controlling the release of the drug comprising mainly ethyl cellulose and containing a water-insoluble powdered substance. Document 4 also states that the time from administration of the medication to initial release of the drug (lag time) can be controlled with good repeatability by adjusting the type and amount of the water-insoluble powdered substance contained in the film for controlling the release of the drug (claim 1, Par. No. 0070). In addition, document 4 lists magnesium stearate, hydrogenated oil, carnauba wax and the like as water-insoluble powdered substances (claim 2), and it also describes a drug controlled release capsule preparation wherein two or more types of drug controlled release tablets with different lag times are contained therein (claims 6-12).

Therefore, this authority finds that persons skilled in the art can easily conceive of taking the inventions described in documents 2 and 3, adding the water-insoluble powdered substance described in document 4 to the film to control the lag time with good repeatability and mixing pharmaceutical preparations with different lag times to make a capsule product and pharmaceutical preparation packaged product. Moreover, this authority finds that no particularly outstanding effect is thus provided.